



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Hugh R. Sharkey et al. Art Unit : 3739
Serial No. : 09/664,473 Examiner : David M. Shay
Filed : September 18, 2000
Title : IN VIVO FORMED THERMALLY CONTRACTED COLLAGEN TISSUE

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Applicant herewith files this Brief on Appeal, thus perfecting the Notice of Appeal which was originally filed on January 23, 2004. The headings and sections required by 37 CFR 1.192 follow:

(1) Real Party in Interest

The application is currently assigned to Smith & Nephew, Inc., who is, hence, the real party-in-interest.

(2) Related Appeals and Interferences

There are no known related appeals or interferences.

(3) Status of Claims

Claims 57-66 are pending. Each of these claims are rejected and appealed.

(4) Status of Amendments

A Response after Final was filed on June 30, 2003. In a subsequent Advisory Action, dated July 28, 2003, the Patent Office indicated that the Response after Final had been considered and did not place the application in condition for allowance.

(5) Summary of Invention

The present method relates to applying a controlled amount of RF thermal energy *in vivo* to vascularized, densely collagenous tissue of at least a portion of a ligament, tendon or joint capsular tissue which interconnects portions of a body. Fig. 1B, for example, shows such a method. As explained in the last paragraph of page 9 and the first paragraph of page 13, the RF thermal energy is applied to thermally modify the tissue to achieve a controlled modification of a geometry, for example, shrinkage, of the tissue. As explained in the last paragraph of page 11,

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contraction of the tissue tightens the interconnection between two portions of the body naturally joined by a region of collagen fibril connective tissue.

As explained in the last paragraph of page 9, the method includes heating the tissue with the applied thermal energy to a temperature in the ranges of about 45 to 75°C, about 50 to 70°C, and about 55 to 65°C.

Figs. 3 and 5, for example, each show a probe having an electrode for applying RF thermal energy to tissue. As explained in the first full paragraph of page 16, applying a controlled amount of RF thermal energy includes advancing the probe to a surgical site containing the tissue. The method can include deflecting a distal end of the probe, and the method can include moving a distal end of the probe over the tissue in painting strokes.

As explained in the first full paragraph of page 10, the tissue can include at least a portion of a medial side ligament of a patella, and the tissue can include at least a portion of a patella tendon allograft.

As explained in the third full paragraph of page 9, modifying the geometry of the tissue can include increasing a cross-sectional diameter of collagen fibrils of the tissue and decreasing a longitudinal length of collagen protein molecules of the tissue.

(6) Issues

Are claims 57-66 properly rejected under 35 U.S.C §103 as being unpatentable over Sand ('709) in combination with Makower et al.?

(7) Grouping of Claims

None of the claims rise and fall together besides those specifically stated herein. Claims 57-62 rise and fall together.

(8) Argument

Rejection of claims 57-62 under 35 U.S.C §103 as being unpatentable over Sand ('709) in combination with Makower et al.

Sand describes using laser energy to shrink collagen tissue. *See* the abstract of Sand. Makower describes using laser energy or RF energy to ablate tissue. *See* Makower at the last paragraph of page 19. The Examiner has taken the position that Makower's description of the use of laser energy or RF energy to ablate tissue would suggest to one of ordinary skill in the art

that RF energy can replace laser energy in Sand's description of shrinking collagen tissue. The Examiner is relying on hindsight. Importantly, Makower does not state that laser energy and RF energy are "equivalent," and does not refer to any tissue effect other than ablation to which both laser energy and RF energy are applicable. Simply stated, neither reference describes or suggests the use of RF energy to shrink collagen tissue.

The faulty reasoning in the Examiner's statement that the "systems of Makower et al and Sand both seek to heat tissue in a controlled manner, thus clearly the equivalence of laser and RF to heat tissue in the method [of] Makower et al would suggest [to] one having ordinary skill in the art that they are equivalent in the method of Sand," is illustrated by the following example:

Two references both seek to cook food, one reference describes that hot dogs can be boiled in the microwave or stove top, the other reference describes boiling eggs stove top. According to the Examiner's reasoning, it would be obvious to one of ordinary skill in the art to boil an egg in the microwave. However, unless special precautions are taken, i.e., poking a hole in the egg shell, the egg explodes. Clearly the "equivalence" of microwave and stove top boiling of a hot dog does not make obvious the boiling of an egg in the microwave rather than stove top. By the same reasoning, the Examiner's stated "equivalence" of laser energy and RF energy to ablate tissue does not make obvious the shrinking of collagen tissue with RF energy rather than laser energy.

Applicants further traverse the Examiner's assertion that to employ RF energy in the method of Sand ('709) "is not critical." The Examiner was apparently taking the position that since Makower describes using laser energy or RF energy to ablate tissue, the selection of laser or RF energy in any type of tissue treatment is not critical. However, there is no description or suggestion in either reference that RF energy can replace laser energy to shrink collagen tissue.

In the Advisory Action, the Examiner states:

[A]ttempts to create analogy between two types of controlled heating (Makower et al and Sand) and two types of uncontrolled heating (hot dog and egg) are not convincing as they are non analogous.

The Examiner is mistaken. Makower describes the use of RF energy or laser energy to ablate tissue (A or B to do C). Sand describes the use of laser energy to shrink collagen tissue (B to do D). One reference seeking to cook food describes the use of a stove top or a microwave to

boil a hot dog (A' or B' to do C'). The other reference seeking to cook food describes the use of a stove top to boil an egg (B' to do D'). According to the hypothetical, the microwave cannot be used to boil an egg (A' cannot do D'), thus illustrating the faulty reasoning in the Examiner's assertion that it would be obvious to use RF energy to shrink collagen tissue (A to do D). In fact, the hypothetical presented is even a closer case than that presented by the Examiner, since both references are seeking to boil food, whereas, in the Examiner's rejection, Makower is seeking to ablate tissue and Sand is seeking to shrink tissue. The hypothetical clearly illustrates the error in the Examiner's analysis, i.e., that by applying reasoning analogous to that applied by the Examiner in the rejection, one would conclude that a microwave can be used to boil an egg, a process that results in an explosion.

Furthermore, tissue ablation is significantly different than tissue shrinkage. Tissue ablation seeks to destroy tissue, whereas tissue shrinkage modifies tissue without destroying the tissue. Neither Makower nor Sand describes or suggests how one would implement applying RF energy to shrink tissue rather than destroy tissue. This is analogous to not knowing the need to poke a hole in the egg to be able to microwave the egg.

The Examiner further states in the Advisory Action: "Basis of lack of criticality is based on applicants originally filed disclosure see page 9, lines 25-26." However, page 9, lines 25-26, which list thermal energy sources other than RF, say nothing about laser energy, and thus lack of criticality between RF energy and laser energy cannot be based on applicants' disclosure.

Furthermore, the Makower reference does not describe or suggest the claimed use of RF energy to achieve a controlled modification of a geometry of tissue. The only tissue effect Makower describes achieving using an RF source with Makower's apparatus is ablation – that is removal of tissue – something that the application excludes from the definition of modification of tissue geometry. See, e.g., applicants' disclosure at page 11, lines 11-12, page 13, line 30 to page 14, line 1, and page 17, lines 4-5.

Rejection of claim 63 under 35 U.S.C §103 as being unpatentable over Sand ('709) in combination with Makower et al.

The Examiner's rejection states: "It would have been obvious to artisan of ordinary skill... to employ a painting motion [in the method of Sand], since this would allow a substantial

length of the tendon to be treated all at once.” Neither Sand nor Makower describes or suggests moving a distal end of a probe over tissue in painting strokes. Furthermore, claim 63 does not recite a tendon, and Sand and Makower do not describe treating a tendon. Thus, there is no description or suggestion in either reference to support the Examiner’s contention that it would be obvious to employ a painting motion to treat all of a tendon at once.

Rejection of claim 64 under 35 U.S.C §103 as being unpatentable over Sand ('709) in combination with Makower et al.

Neither the Sand reference nor the Makower references describes or suggests that the tissue is at least a portion of a medial side ligament of a patella. While Sand describes that the laser system is applicable to the field of musculoskeletal injuries, Sand does not describe or suggest treating a portion of a medial side ligament of a patella.

Rejection of claim 65 under 35 U.S.C §103 as being unpatentable over Sand ('709) in combination with Makower et al.

The Examiner’s rejection states “It would have been obvious to artisan of ordinary skill... to employ the method on patellar tendons, since Sand ('709) does not discuss avoiding these structures.” Neither Sand nor Makower describes or suggests that the tissue is at least a portion of a patella tendon allograft. Such a lack of disclosure does not support an obviousness rejection.

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A check for the brief fee and an extension of time fee is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Phyllis K. Kristal
Phyllis K. Kristal
Reg. No. 38,524

Fish & Richardson P.C.
1425 K Street, N.W.
11th Floor
Washington, DC 20005-3500
Telephone: (202) 783-5070
Facsimile: (202) 783-2331

Appendix of Claims

57. A method, comprising:
- applying a controlled amount of RF thermal energy *in vivo* to vascularized, densely collagenous tissue of at least a portion of a ligament, tendon or joint capsular tissue which interconnects portions of a body to thermally modify the tissue to achieve a controlled modification of a geometry of the tissue.
58. The method of claim 57 further comprising heating the tissue with the applied thermal energy to a temperature in the range of about 45 to 75°C.
59. The method of claim 57 further comprising heating the tissue with the applied thermal energy to a temperature in the range of about 50 to 70°C.
60. The method of claim 57 further comprising heating the tissue with the applied thermal energy to a temperature in the range of about 55 to 65°C.
61. The method of claim 57 wherein applying includes advancing a probe having an electrode to a surgical site containing the tissue.
62. The method of claim 61 further comprising deflecting a distal end of the probe.
63. The method of claim 62 further comprising moving a distal end of the probe over the tissue in painting strokes.
64. The method of claim 57 wherein the tissue comprises at least a portion of a medial side ligament of a patella.
65. The method of claim 57 wherein the tissue comprises at least a portion of a patella tendon allograft.

66. The method of claim 57 wherein modifying the geometry of the tissue includes increasing a cross-sectional diameter of collagen fibrils of the tissue and decreasing a longitudinal length of collagen protein molecules of the tissue.